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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,129	04/11/2001	Michele Fiscella	PZ045P1	1593

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	7

DATE MAILED: 04/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/832,129	Applicant(s) FISCELLA ET AL.	
	Examiner Hope A. Robinson	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Serial Number 09/832,129
Art Unit 1653

Restriction/Election

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

2. This application contains claims directed to several patentably distinct DNA and protein sequences deemed as separate inventions, therefore, an election of one sequence (the DNA and the encoding protein)is required from Table 1. This is not a species election.

Groups 1-23, claim(s)1-10, 14 and 21 all in part, drawn to an isolated nucleic acid of SEQ ID NO: X (SEQ ID NOS: 11-33)or a peptide of SEQ ID NO: Y (SEQ ID NOS: 34-56), wherein X and Y are values that correlate to those listed in Table 1, and correspond to one of the cDNA Clone IDs, respectively, classified in class 536, subclass 23.1. For example,

If Group 1 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33 of Table 1, wherein X is 11 and Y is 34.

If Group 2 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33, wherein X is 30 and Y is 53.

Groups 24-46, claim(s) 11-12 and 15, all in part, each group directed to an isolated polypeptide of SEQ ID NO: Y, wherein Y correlates to one of those listed in Table 1 (SEQ ID NOS: 34-56), and corresponds to one of the cDNA Clone IDs, respectively, classified in class 530, subclass 350. For examples,

If Group 24 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33 of Table 1, wherein Y is 34.

If group 25 is elected, this correlates to Gene No. 1, cDNA clone ID

HOFOC33, wherein Y is 53.

Groups 47-69, claim 13, in part, drawn to an isolated antibody which binds to a protein with SEQ ID NO: Y, wherein Y correlates to one of those listed in Table 1, and corresponds to one of the cDNA Clone IDs, respectively, classified in class 530, subclass 387.1. For examples,

If group 47 is elected, this correlates to Gene No 1, cDNA clone ID HOFOC33 of Table 1 (SEQ ID NOS: 34-56), wherein Y is 34.

If group 48 is elected, this correlates to Gene No 2, cDNA clone ID HOFOC33, wherein Y is 53.

Groups 70-92, claim 15, in part, drawn to a method of making an isolated polypeptide of SEQ ID NO: Y, wherein Y correlates to one of those listed in Table 1 (SEQ ID NOS: 34-56), and corresponds to one of the cDNA Clone IDs, respectively, classified in class 435, subclass 69.1. For examples,

If group 70 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33 of Table 1, wherein Y is 34.

If group 71 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33, wherein Y is 53.

Groups 93-115, claim 17, in part, drawn to a method for preventing, treating or ameliorating an undefined medical condition by administering a polypeptide of SEQ ID NO: Y, wherein Y correlates to one of those listed in Table 1 (SEQ ID NOS: 34-56), and corresponds to one of the cDNA Clone IDs, respectively, classified in class 514, subclass 2+. For examples,

If group 93 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33 of Table 1, wherein Y is 34.

If group 94 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33, wherein Y is 53.

Groups 116-138, claim 17, in part, drawn to a method for preventing, treating or ameliorating an undefined medical condition by administering a polynucleotide of SEQ ID NO: X, wherein X correlates to one of those listed in Table 1 (SEQ ID NOS: 11-33), and corresponds to one of the cDNA Clone IDs, respectively, classified in class 514, subclass 44. For examples,

If Group 116 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33 of Table 1, wherein X is 11.

If Group 116 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33, wherein X is 30.

Groups 139-161, claim 18, in part, drawn to a method of diagnosis of a pathological condition by determining the presence or absence of a mutation in a polynucleotide of SEQ ID NO: X, wherein X correlates to one of those listed in Table 1 (SEQ ID NOS: 11-33), and corresponds to one of the cDNA Clone IDs, respectively, classified in class 435, subclass 6. For examples,

If Group 139 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33 of Table 1, wherein X is 11.

If Group 140 is elected, this correlates to Gene No. 2, cDNA clone ID HOFOC33, wherein X is 30.

Groups 162-184, claim 19, in part, drawn to a method of diagnosis of a pathological condition by determining the presence or absence of a mutation in a polypeptide of SEQ ID NO: Y, wherein Y correlates to one of those listed in Table 1, and corresponds to one of the cDNA Clone IDs, respectively,

classified in class 435, subclass 7.1. For examples,

If group 162 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33 of Table 1, wherein Y is 34.

If group 163 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33, wherein Y is 53.

Groups 185-207, claim 20, in part, drawn to a method of identifying a binding partner to a polypeptide defined by SEQ ID NO: Y, wherein Y correlates to one of those listed in Table 1, and corresponds to one of the cDNA Clone IDs, respectively, classified in class 435, subclass 7.8. For examples,

If Group 185 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33 of Table 1, wherein Y is 34.

If Group 186 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33, wherein Y is 53.

Groups 208-230, claims 22-23, in part, drawn to a method of identifying an activity in a biological assay by identification of the protein in the supernatant wherein the cell expresses a polypeptide encoded by SEQ ID NO: X, wherein X correlates to one of those listed in Table 1 (SEQ ID NOS: 11-33), and corresponds to one of the cDNA Clone IDs, respectively, classified in class 436, subclass 501. For examples,

If Group 208 is elected, this correlates to Gene No. 1, cDNA clone ID HOFOC33 of Table 1, wherein X is 11.

If Group 209 is elected, this correlates to Gene No. 2, cDNA clone ID HOFOC33, wherein X is 30.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Groups 1-23 are related to the proteins of Groups 24-46 by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Groups 24-46 are related to the antibodies of Groups 47-69 II by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of Groups 1-23 and the antibody of Groups 47-69 are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

The products of Groups 1-69 are separate and distinct from the methods of Groups 70-230, however, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP 806.05(h). In the instant case the DNA can be used in a hybridization assay.

The methods of Groups 70-230 are unrelated. Inventions are unrealted if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP 806.04 and MPEP 808.01). In the instant case the methods are patentably distinct because they have different method steps, products and having different end results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, the inventions have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, election of a single group for examination purposes as indicated is proper.

A telephone call was made to Ms. Janet Martineau on March 28, 2003 to request an oral election to the above requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:00 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

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Hope A. Robinson, MS

Patent Examiner

Christopher S. F. Low

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